

May 6, 2022



VIA ELECTRONIC MAIL

Robert C. McConkey, III
Assistant United States Attorney
United States Attorney's Office for the Eastern District of Tennessee
800 Market Street, Suite 211
Knoxville, TN 37902

Re: *United States & State of Tenn. v. Walgreen Co.*, No. 21-cv-00080-JRG-CRW (E.D. Tenn.) – 30(b)(6) Deposition Topics

Dear Rob:

We write to address the topics in Walgreens Co.'s ("Walgreens") Notice of Deposition to the Centers for Medicare and Medicaid Services ("CMS") dated January 21, 2022.

Topics 2, 3, 4, 7, 8, 9, 10, 11, 12, and 27

The parties have exchanged their positions on these topics and appear to be at an impasse. We intend to move to compel the United States to provide testimony on these topics.

Topics 1, 5, 6, and 13-26

Walgreens rejects the United States' assertion that Topics 1, 5, 6, and 13-26 do not comply with Rule 30(b)(6) due to a lack of "reasonable particularity." While we disagree, we provide you with more information in this letter. If you want to discuss further, please contact us by email by no later than one week from the date of this letter; otherwise, we will reasonably presume that this additional information satisfies the issues you raised.

The United States raised many of the same or similar questions regarding multiple topics. For the sake of efficiency, we address each of these repeat issues first. To the extent our responses involve modifications of existing topics, we will send you a revised notice early next week.

- **Deliberative process privilege.** Walgreens is not seeking information that is in fact protected by the deliberative process privilege. Consistent with our motion to compel discovery from the United States dated May 5, 2022, *see* Dkt. 116, the subject matter of

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these topics calls for non-privileged information. For example, final decisions regarding a given subject matter, and actions taken for the purpose of implementing those decisions, are by definition not predecisional and thus not privileged. *United States Fish & Wildlife Service v. Sierra Club, Inc.*, 141 S. Ct. 777 (2021). Moreover, the deliberative process privilege only covers communications that are part of the deliberative process; it does not cover the *facts* of when, by whom, how, and why a particular decision was debated and made (much less implemented). *Parke, Davis & Co. v. Califano*, 623 F.2d 1, 5 (6th Cir. 1980).

- **Overbreadth objections regarding “including, but not limited to” language.** For efficiency purposes, we have stricken the “but not limited to” language in order to address your objections.
- **Overbreadth objections regarding non-CMS component agencies of HHS.** We agree that testimony about the preservation of information related to non-CMS component agencies’ activities, and testimony about the activities themselves, are out-of-scope if that information is not relevant to this case. However, to the extent CMS consulted with non-CMS component agencies in relation to the subject matter of a particular topic, that would be relevant.
- **Relevant time period and drugs.** Walgreens agrees to limit the time period for Topics 15 through 25 to January 1, 2010 through December 31, 2016.

As Walgreens has explained to the government on multiple occasions, Walgreens’ use of a longer time period for certain topics addresses that the FDA started to approve Hepatitis C DAAs in or around 2011. One of Walgreens’ defenses is that TennCare broke federal law by limiting access to Hepatitis C DAAs on the basis of fibrosis and sobriety. Walgreens expects that the process by which TennCare arrived at the prior authorization criteria at issue in this suit began not in late 2014, by which time at least two of the Relevant Drugs were on the market and covered by TennCare, but rather much earlier, when these drugs and their predecessor DAA therapies were under development and were first coming to market. As such, information starting in 2010 is relevant to Walgreens’ ability to demonstrate that TennCare’s prior authorization criteria for Hepatitis C drugs violate federal law.

For similar reasons, and in light of the relevance of the Four DAAs’ clinical superiority over other Hepatitis C medications, the Four DAAs are not the only relevant drugs for purposes of Walgreens’ defenses based on CMS Release No. 172 and Section 1927 of the Social Security Act. Nonetheless, for the sake of narrowing the issues in dispute between the parties, we will limit the relevant drugs to the Four DAAs and Other DAAs (as defined in the Notice) for Topics 16, 18, 20, 21, 22, and 24. Non-DAAs remain relevant to Topic 19, however, as that topic explicitly deals with the clinical superiority of the Four DAAs over any other Hepatitis C medication.

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- **The United States' requests for "sample questions."** Walgreens has no obligation to provide, and no intention of providing, the United States with "sample questions [we] intend to ask the witnesses" on any of the below topics. Ltr. at 4. The original topics and the clarifications in this letter provide the United States with ample notice of the "matters for examination." Fed. R. Civ. P. 30(b)(6). We are not aware of any authority in support of your request for sample questions.

The remainder of this letter addresses objections and requests for clarification specific to individual Topics.

- **Topic 1:** Topic 1 does not refer to "custodians/relevant witnesses," and it is your responsibility to designate one or more witnesses prepared to testify on this topic. We can hardly provide you with a list of custodians we think are relevant to Topic 1 given that, nine months after our first RFPs, you have not given us a list of custodians you are searching for purposes of document review and production. As for your request for "the specific organizational sections/divisions within CMS to which you are referring," information about which divisions of CMS house the relevant document repositories is uniquely within the United States' possession. As for the types of "databases, systems, and servers" to which we are referring in Topic 1, the specific identities of those systems are also uniquely within the United States' knowledge, but generally speaking we are interested in email repositories, other sources of ESI (such as hard drives and network drives), databases (such as claims and financial databases), and hard-copy document repositories.
- **Topic 5:** Walgreens is seeking information about any and all investigations that preceded this Action, whether conducted or contributed to by TBI, TennCare, the Tennessee Attorney General's Office, the U.S. Attorney's Office for the Easter District of Tennessee, and/or Main Justice (as it concerns the TennCare allegations in particular). Regarding the government's request for Walgreens to specify the "information" to which it is referring in this topic, Walgreens is seeking testimony about the circumstances under which any information regarding the initiation, scope, findings, investigative activities, and/or conclusions reached in any of the investigations that preceded this Action were communicated to CMS. Regarding the government's request for Walgreens to describe "the specific issues [it is] interested in," Walgreens directs the government's attention to the text of Topic 5, which makes clear that Walgreens seeks testimony regarding the identities of the persons who transmitted information to CMS about the investigation, and the identities of the persons at CMS who received the information; the entities CMS communicated with about the information; the means used to communicate the information; what information was communicated; and when that information was communicated. We decline your request that we provide the identities of "specific persons from whom [we] would like responsive information," or "[a] list of sample questions that [we] intend to ask relating to this topic." All of that information is squarely and properly within the scope of your obligations to identify and prepare one or more witnesses to testify on this topic.

- **Topic 6:** We are perplexed, to say the least, by your request for “the specific types of ‘information’ for which [we] seek responsive information, including identifying any specific allegations made by the government and/or defenses raised by Walgreens in which you may be interested.” It troubles us that the United States does not already know who within its own healthcare agency may have information relevant to this healthcare matter that the government investigated for five years prior to filing suit. Notwithstanding these concerns, the information that Walgreens deems within the scope of Topic 6’s reference to “information relevant to this Action” encompasses facts relating to any of the claims raised by the government in its Complaint, to Walgreens’ affirmative defenses, to facts learned and steps taken by the United States in the course of the investigation(s) that preceded this Action that bear on the claims and defenses in the case, and to the United States’ responses to Walgreens’ discovery requests issued to date.
- **Topic 13:** Regarding “federal financial participation in Medicaid,” Walgreens is seeking testimony regarding the federal government’s involvement in reviewing, funding, assisting, evaluating or otherwise participating in TennCare’s prescription drug benefit.
- **Topic 14:** Regarding Walgreens’ request for testimony on the locations of documents referenced in Topic 13, Walgreens is seeking information about the location of email repositories, other sources of ESI (such as hard drives and network drives), databases (such as claims and financial databases), and hard-copy document repositories, and is seeking details regarding the servers, folders, drives, files, and/or other repositories in which the information is stored.
- **Topic 15:** As outlined in Topic 15, Walgreens is seeking testimony regarding the federal government’s involvement in reviewing, funding, assisting, evaluating or otherwise participating in TennCare’s prescription drug benefit. We affirm that the terms “nature, structure, administration and oversight” are defined by their ordinary, independent meaning and we expect CMS representative(s) designated by the United States will be prepared to testify regarding all aspects of Topic 15.
- **Topic 17:** Walgreens affirms that the terms “development,” “drafting” and “promulgation” are defined by their ordinary, independent meaning, and we expect the CMS representative(s) designated by the government will be prepared to testify regarding all aspects of Topic 17.
- **Topic 18:** Walgreens confirms that it will not seek testimony about information that is in fact covered by the attorney-client privilege; however, this Topic is not limited to such information. For example, if CMS has analyses or other information that were compiled without the assistance of legal counsel and not for the purpose of providing legal advice, then those analyses would by definition not be privileged. Finally, information pertaining to state Medicaid programs other than TennCare is relevant to Walgreens’ defenses to the

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extent that CMS concluded that other state Medicaid programs with sobriety and/or F-score restrictions similar to those in place in Tennessee were noncompliant with the Social Security Act.

- **Topic 24:** With respect to the government’s query regarding the meaning of “budgetary implications of the waiver,” Walgreens is seeking information regarding the impact that granting the alleged TennCare waiver had, and the impact it was expected to have, on the budgets of both CMS and TennCare for the provision of Medicaid services to Tennessee patients. Such testimony is directly relevant to the government’s assertions that the alleged waiver made it proper for TennCare to make decisions regarding drug coverage based on cost. *See ECF 42 at 8 (government claiming in opposition to Walgreens’ supplemental motion to dismiss that “the CMS Special Terms and Conditions . . . attendant to TennCare’s Waiver Letter, also memorialize the expectation that TennCare will consider cost as a factor when determining which drugs to cover”).*
- **Topic 25:** Regarding your representation that “CMS does not perform utilization management functions for Medicaid covered outpatient drugs,” please confirm whether CMS did not, in fact, perform any utilization management reviews or audits of TennCare in particular in the relevant period.

Sincerely,



Michael R. Dziuban

cc: Jef Feibelman
Jon Lakey
David M. Rudolph
W. Anthony Hullender
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